IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re Entresto (Sacubitril/Valsartan) Patent Litigation	C.A. No. 20-2930-RGA
NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, MSN LIFE SCIENCES PRIVATE LIMITED, NANJING NORATECH PHARMACEUTICAL CO., LIMITED, Defendants.	C.A. No. 22-1395-RGA

DEFENDANTS' POST MARKMAN HEARING - SUPPLEMENTAL BRIEFING

In response to the Court's request to locate "[t]he best Federal Circuit case … for the idea that a series of terms in a specification should be read as mutually exclusive" (*Markman* Tr. at 54:6–15), Defendants respectfully identify *Duke Univ. v. BioMarin Pharm. Inc.*, 685 F. App'x 967 (Fed. Cir. 2017) and *Perfect Surgical Techniques, Inc. v. Olympus Am., Inc.*, 841 F.3d 1004 (Fed. Cir. 2016).

As an initial matter, it is important to clarify where the parties are aligned; the parties agree that the claims of the '918 patent do *not* cover *any* possible solid form of a compound that is a complex of TSV formed by noncovalent bonds. Instead, the claims are directed to the specific amorphous solid form, which is one of the four solid forms disclosed in the specification. Joint Br., Ex. 1, ('918 Patent) at 17:41–45 ("In the solid state [the compound] can be in the crystalline, partially crystalline, *amorphous*, or polymorphous form, preferably in the crystalline form."). And Novartis admits these are four distinct solid forms with distinct meanings. Joint Br. at 30; *Markman* Tr. at 54:1–5. Nevertheless, and the reason why there is a claim construction dispute before the Court, Novartis alleges that the plain and ordinary meaning of "amorphous solid form of a compound" encompasses unclaimed, non-amorphous solid forms of TSV so long as the unclaimed solid forms contain "trace amounts" of an amorphous solid form of TSV. But Novartis's interpretation is predicated on the Court eliminating any meaningful distinction between a "crystalline" solid form of a compound, a "partially crystalline"/partially amorphous solid form of a compound, and an "amorphous" solid form of a compound. *See, e.g.*, *Markman* Tr. at 6:8–15. This is incorrect as a matter of law. Just as "crystalline" is not partially crystalline, "amorphous" is not partially amorphous—and "amorphous" is certainly *not* "crystalline." Rather, the intrinsic evidence confirms these are mutually exclusive solid forms of the compound, only one of which was claimed. Joint Br. at 11–20, 36–43. Thus, Federal Circuit law compels a construction that maintains the mutual exclusivity of the solid forms instead of conflating them.

In *Duke Univ.*, the Federal Circuit reviewed the construction of the term "a precursor of recombinant human acid α-glucosidase [i.e., "hGAA/rhGAA"]." *Duke Univ*., 685 F. App'x at 969. The PTAB construed the term to cover both precursor and non-precursor forms. Specifically defining the term, "to mean any precursor of recombinant hGAA (e.g., a 110-kD form) that is exclusively produced in CHO cell cultures," and not limiting the claim to "exclusively precursor rhGAA." *Id.*; *see also Biomarin Pharm. Inc., Petitioner, v. Duke Univ., Pat. Owner.*, No. IPR2013-00535, 2015 WL 1009196, at *4 (PTAB Feb. 23, 2015) ("Neither claim 1 nor claim 9 precludes administering a non-precursor form of hGAA or rhGAA… and are not limited to administering exclusively a precursor form and no other form.").

The Federal Circuit held the PTAB's construction—which mirrored the construction the patentee advanced before the PTAB—was overly broad and improper in view of the intrinsic evidence, holding "that the proper construction of 'precursor' in claim 9 is '*exclusively* a precursor of recombinant hGAA that has been produced in CHO cell cultures.'" *Id.* at 975 (emphasis added). The Federal Circuit noted that the specification confirmed the "precursor" form of hGAA was a distinct form of hGAA among other unclaimed forms, so it must be construed as mutually exclusive of unclaimed forms, stating:

> *The patent repeatedly refers to "precursor" as a 'form' of [h]GAA*…it states: "In the methods of the invention, human acid α-glucosidase (GAA) is administered to the individual. The GAA is in *a form* that, when administered, targets tissues…*In one preferred embodiment, the human GAA is administered in its precursor form*…Alternatively**,** a *mature form* of human GAA…can be administered. In a particularly preferred embodiment, the GAA is the *precursor form* of recombinant human GAA."…Thus, the written description also supports a conclusion that 'precursor' in claim 9 refers to *exclusively* a precursor form of hGAA. The Board erred in concluding otherwise.

Id. at 976 (underlined emphasis in original; other emphasis added).

The present claim construction dispute closely parallels *Duke Univ.* Both cases feature a disputed term that is a specific form of a compound—an amorphous solid form of the "compound" here, and a precursor form of hGAA/rhGAA in *Duke Univ.* As with *Duke Univ*., Novartis's broader claims to the "compound," which did *not* specify a particular solid form of the compound (or a solid form at all), were not limited to a particular solid form by this Court. *Compare Duke Univ.*, 685 F. App'x at 975–76 *with In re Entresto (Sacubitril/Valsartan) Pat. Litig.*, No. 20-MD-2930-LPS, 2021 WL 2856683, at *4–5 (D. Del. July 8, 2021) ("While claim 1 of the '938 patent explicitly *requires [TSV] in crystalline form*, claim 1 of the '134 patent ***does not***…The specification of the '134 patent teaches that the compound of the claims 'can be in the crystalline, partially crystalline, amorphous, or polymorphous form, preferably in the crystalline form' ('134 patent at 15:63–67), *all of which suggests that the claimed compound is not always and necessarily in crystalline form*." (emphasis added)). Moreover, here, like in *Duke Univ.*, Novartis has claimed a specific form of the compound—an amorphous solid form—to the exclusion of other, unclaimed forms. *Compare* '918 patent claim 1, *with* '918 patent col. 17 ll. 41–45 (confirming Novartis claimed only the amorphous solid form of the compound to the exclusion of "crystalline" and "partially crystalline"/partially amorphous solid forms).

Indeed, the intrinsic evidence here is even more compelling than that in *Duke Univ.*, because, in addition to the specification confirming Novartis claimed a discrete solid form of the compound to the exclusion of other solid forms recited in the specification, Novartis argued repeatedly during prosecution to secure allowance of the '918 patent that crystalline solid forms discussed in the prior art have no relevance to and do not overlap with the claimed "amorphous solid form" because they are distinct forms and *counterparts*. *E.g.*, Joint Br. Ex. 9 (Cima Decl.) at ¶ 18 ("Rodriguez-Spong notes that an amorphous solid form of a compound can exhibit greater solubility or bioavailability than the *crystalline solid form of the same compound*… ('amorphous solids present an attractive approach…compared to their *crystalline counterparts*'….; (emphasis in original)); *id.* at ¶¶ 11–17 (stating, *inter alia*, "Morissette states that '[co]-crystals have the potential to be much more useful in pharmaceutical products than solvates or hydrates'…*However, this is not pertinent or informative with respect to amorphous solids*." (emphasis added)); *see also* Trial Tr. (Park) at 566:9–23 (testifying "crystalline material has long-range three-dimensional order" and "amorphous material, on the other hand, doesn't have a specific long-range order"). Thus, as with *Duke Univ*., the Court must construe "an amorphous solid form of a compound" in

a manner that excludes the unclaimed solid forms recited in the specification of the '918 patent from its scope because the intrinsic evidence "supports a conclusion that [an amorphous solid form of a compound] in claim [1] refers to exclusively a[n] [amorphous solid] form of [TSV]." *Duke Univ.*, 685 F. App'x at 976; *see also Perfect Surgical Techniques, Inc.*, 841 F.3d at 1013 ("We conclude that the specification's separation of the terms perforated and passages with the disjunctive phrase 'or otherwise' makes clear that the patentee intended that the term 'perforated' is not the same as 'passages.' The patentee claimed only jaws that are 'perforated'; this claim does not extend to passages. In light of the intrinsic record, we conclude that the term 'perforated' is not coextensive with or the same as 'passages.'"); *Ethicon Endo-Surgery, Inc. v. U.S. Surg. Corp.*, 93 F.3d 1572, 1573 (holding that elements "pusher bar" and "pusher assembly" are not synonyms and the terms they have different meanings even if the "pusher assembly" includes the "pusher bar").

These cases, in combination with the intrinsic evidence here, support a construction of "amorphous solid form" that is distinct and exclusive from the unclaimed solid forms recited in the '918 patent. Accordingly, like this Court did when it construed crystalline solid forms claimed in related patents, an appropriate construction of the '918 patent requires the claim term to be a "substantially pure amorphous solid form of a compound." Joint Br. at 13–17, 21–24. This construction would give consistent meaning to the claim language "form" across the claims of the patent family, render the specification internally consistent, and give meaning to terms recited in the claims and specification, as it would result in "crystalline" and "amorphous" solid forms being at least 90 percent pure, and solid forms less than 90 percent pure being "partially crystalline"/partially amorphous. *Id.*

But if the Court determines that "an amorphous solid form of a compound" is not excluded from also being "partially crystalline"/partially amorphous, the intrinsic evidence compels a construction that, at the very least, explicitly states that "an amorphous solid form of a compound" excludes crystalline solid forms of the same compound from falling within the scope of the term—which Plaintiff's convoluted "plain and ordinary meaning" would improperly allow. Joint Br. at 30; *Markman* Tr. at 54:1–5. Crystalline compounds cannot fall within the scope of the disputed term because, as detailed above, the intrinsic evidence—including in the sworn Rule 132 Declaration filed to secure allowance—confirms the claimed "amorphous solid form of a compound" is distinct from and excludes crystalline solid forms of the compound. *E.g.*, Joint Br. Ex. 9 (Cima Decl.) at ¶¶ 11–18; *SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1122 (Fed. Cir. 1985) (when a patent claim "does not contain a certain limitation and another claim does, that limitation cannot be read into the former claim in determining either validity or infringement."); *see also Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1288 n.10 (Fed. Cir. 2017) ("It is highly disfavored to construe terms in a way that renders them void, meaningless, or superfluous.") (internal citation omitted).

HEYMAN ENERIO
GATTUSO & HIRZEL LLP

/s/ Dominick T. Gattuso
Dominick T. Gattuso (#3630)
Denise S. Kraft (# 2778)
300 Delaware Ave., Suite 200
Wilmington, DE 19801
(302) 472-7300
dgattuso@hegh.law
dkraft@hegh.law

Don J. Mizerk
Matthew M. Kamps
HUSCH BLACKWELL LLP
120 South Riverside Plaza, Suite 2200
Chicago, IL 60606
(312) 655-1500
don.mizerk@huschblackwell.com
matt.kamps@huschblackwell.com

Thomas P. Heneghan
HUSCH BLACKWELL LLP
33 East Main Street, Suite 300
Madison, WI 53703
(606) 234-6032
tom.heneghan@huschblackwell.com

Attorneys for Defendant Nanjing Noratech Pharmaceutical Co., Limited

STAMOULIS & WEINBLATT LLC

/s/ Richard C. Weinblatt
Stamatios Stamoulis (# 4606)
Richard C. Weinblatt (# 5080)
800 N. West Street, Third Floor
Wilmington, DE 19801
(302) 999-1540
stamoulis@swdelaw.com
weinblatt@swdelaw.com

Ronald M. Daignault*
Richard Juang*
DAIGNAULT IYER LLP
8618 Westwood Center Drive, Suite 150
Vienna, VA 22182
rdaignault@daignaultiyer.com
rjuang@daignaultiyer.com
**Not admitted in Virginia*

Attorneys for Defendants MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited

Dated: March 22, 2024